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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MCKELVEY, TERRY ALAN	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 11/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/834,095	KAWAOKA, YOSHIHIRO	
	Examiner	Art Unit	
	Terry A. McKelvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) *7,8 and 10-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6,7,10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, species M2 protein, claims 1-6, 9, and 25-26 in Paper No. 9, filed 8/7/02 is acknowledged. The traversal is on the ground(s) that the inventions are so closely related within the context of the disclosure that they cannot be properly considered independent and distinct because the elected claims are clearly related. It is also argued that restriction requirements are optional in all cases and that if the search and examination of an entire application can be made without a serious burden, the Examiner must examine it on the merits. The applicant argues that due to the relatedness of the subject matter in at least Groups I-III, the claims in at least Groups I-III can be efficiently and effectively searched in a single search with no additional burden placed on the Examiner. This is not found persuasive because "relatedness" is not the standard for determining whether a restriction is proper, independence or distinctness, and burden, constitute the standard, as set forth in the previous communication. The inventions of the five groups are distinct from each other for the reasons previously set forth. The different classifications of the groups are prima facie

evidence of burden to search and examine together. The search for Groups II-III would require a search of additional class/subclasses, which class/subclasses are not required to be searched for the search of the elected group, Group I. Searching either of these additional class/subclasses constitutes an undue burden if done in combination with the search for Group I. For the two groups that are classified same (Groups IV-V), because the full search of both groups requires different non-patent literature searches due to very different chemical compounds being searched (different vectors), it would be a burden to search them together. The restriction requirement is optional based upon the examiner's option, not the applicant's option, as long as the standard for restriction is met as described above and in the previous communication.

The applicant also argues that the requirement for the election of species is traversed on the basis that the species M2 protein, NB protein, and CM1 protein have a disclosed relationship, they are ion channel proteins of influenza types A, B, and C respectively. This argument is not persuasive because of course the three species are related, because they are species of each other and thus are related in some fashion, such as function. Their different structures makes them

patentably distinct species: M2, NB, and CM1 have sequences that are different from each other.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7-8, and 10-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The oath/declaration specifically indicates that no claim for priority for the benefit under 35 USC 119(e) is being made at the time. This is incorrect because at the time of the signing of and the filing of the oath/declaration a claim to priority under 119(e) was being made as indicated by the claim for priority to a provisional application in the first sentence

of the application, made at the time of the filing of the application, 4/12/01.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 25-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of "Isolated virus" in claim 25 renders the claims vague and indefinite because it is unclear whether the metes and bounds of the claim is intended to be one virus being claimed, in which case the claim should recite "An isolated virus ..." or, if the plural is intended, how many viruses are being claimed, i.e., the number of viruses that are encompassed within the term used. It is unclear how many viruses are necessary to meet the claim limitations.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-6, and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Castrucci et al (applicant reference AA1).

Castrucci et al teach an isolated and purified recombinant influenza virus (with the M2 gene derived from cloned cDNA) comprising a mutant M2 protein which has a carboxyl-terminal Glu deletion (page 2726). (The reference teaches infections with only the mutant virus; thus the virus taught must be isolated and purified.) This reference teaches that the recombinant influenza virus having an M gene with the carboxyl-terminal deletion resulted in a 10-fold lower titer in ferrets than the wild type, which suggests that the carboxyl-terminal deletion may have attenuated the virus (page 2726, column 2). This shows that the M2 protein lacks or has reduced activity relative to wild type M2. Castrucci et al also teach host cells contacted with the virus (infection in MDCK cells and in cells in vivo in

a ferret). The recombinant virus taught by the reference reads on a virus made by the method of claim 11 because the method of claim 11 appears to be able to produce any recombinant influenza virus that has a mutant M2 protein encoded by a gene from a cloned cDNA and thus a recombinant influenza virus made by any other method is not different structurally from a virus made specifically by the method of claim 11. Identical products made by different methods read on each other because the products are what is being claimed, not the method of production. In the instant case, there is no evidence that production of a recombinant influenza virus by the method of claim 11 results in a recombinant influenza virus that is in any way different from a recombinant influenza virus produced using a different method. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best,195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada,15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claims 1, 3-4, 6, and 25-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Sweet et al (applicant reference AA2).

Sweet et al teach an isolated and plaque purified recombinant influenza virus (with the M2 gene derived from cloned cDNA) comprising a mutant M2 protein which has a mutation in amino acid 27, 30, or 31 (which is in the transmembrane portion of the protein, page 108, column 2), or three different membrane spanning mutations (pages 107 and 110)). This reference teaches that the recombinant influenza virus having three M2 gene mutations in the membrane spanning region grows less well than clones having one mutation, suggesting that the three mutations may interfere with the normal functioning of the protein (page 110). Sweet et al also teach host cells contacted with the recombinant virus (infection in MDCK cells) (page 107). The recombinant virus taught by the reference reads on a virus made by the method of claim 11 because the method of claim 11 appears to be able to produce any recombinant influenza virus that has a mutant M2 protein encoded by a gene from a cloned cDNA and thus a recombinant influenza virus made by any other method is not different structurally from a virus made specifically by the method of claim 11. Identical products made by different methods read on each other because the products are

what is being claimed, not the method of production. In the instant case, there is no evidence that production of a recombinant influenza virus by the method of claim 11 results in a recombinant influenza virus that is in any way different from a recombinant influenza virus produced using a different method.

Claims 1-2, 5-6, 9, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Park et al (applicant reference AA3).

Park et al teach an isolated and purified recombinant influenza virus comprising a mutant M2 protein which has a deletion of the first 10 amino acids (Figure 2 and page 2452). This reference teaches that the C-terminal residues may play an important role in virus replication because of the author's failure to generate virus (which must be replicating because of the system used) lacking the C-terminal 10 amino acids (pages 2451-2452), and thus the mutant M2 protein must have reduced or no activity relative to the wild type M2 protein. Park et al also teach an isolated and purified recombinant influenza virus that comprises a mutant, chimeric M2 protein that contains only the M2 extracellular domain and the rest of the protein from protein F of a Sendai virus (which is a heterologous protein of a mouse pathogen which, because of its size, is inherently

immunogenic since any protein that is 10 amino acids or more can be immunogenic) (abstract; pages 2452-2453). This mutant M2 protein would inherently lack or have reduced activity because it is missing a part of the M2 protein needed for function (the transmembrane portion).

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning missing attachments or other minor formalities of this communication should be directed to the patent analyst, Zeta Adams, whose telephone number is (703) 305-3291.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is

(703) 305-7213. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

October 29, 2002